

64. 28 The polynucleotide of claim 63, wherein said heterologous polynucleotide encodes a heterologous polypeptide.-- 27

### **Remarks**

The specification has been amended to reflect the change of address for the American Type Culture Collection.

Claims 10-14, 17 and 21-64 are pending in the application. Claims 8, 9, 15, 16, and 18-20 have been canceled without prejudice to or disclaimer of the subject matter therein. New claims 21-64 have been added. Claims 1-7 were canceled in favor of claims 21-64 in order to more precisely define the invention. Support for these new claims can be found throughout the specification and original claims.

More specifically, support for claims 21-33, 44-52 and 56-60 can be found in original claims 1-7. In particular, support for subparagraphs (g)-(l) of new claim 21 and subparagraphs (e)-(h) of new claim 44 can be found in the specification at page 16, lines 20-31, wherein it states:

the polynucleotide sequence may include up to five point mutations per each 100 nucleotides of the reference nucleotide sequence . . . In other words, . . . up to 5% of the nucleotides in the reference sequence may be deleted or substituted with another nucleotide, or a number of nucleotides up to 5% of the total in the reference sequence may be inserted into the reference sequence. These mutations of the reference sequence may occur at the 5' or 3' terminal positions of the reference nucleotide sequence or anywhere between those terminal positions, interspersed either individually among nucleotides in the reference sequence or in one or more contiguous groups within the reference sequence.

Support for claims 53-55 can be found in original claim 1 and SEQ ID NO:1. In particular, the ATG codon that encodes the first amino acid residue (Met) of the Ck $\beta$ -15 polypeptide sequence is at positions 88-90 in SEQ ID NO:1. Similarly, the CTG codon that encodes the last amino acid residue (Leu) of the polypeptide sequence is at positions 532-534 in SEQ ID NO:1. Thus, the nucleotides that encode the first and last amino acid residues of the Ck $\beta$ -15 polypeptide are specifically indicated by the specification. Further, original claim 1(a) recites "a nucleotide sequence encoding a polypeptide comprising amino acids -20 to 129 in SEQ ID NO:2." The first

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nucleotide of the codon that encodes amino acid number -20 in SEQ ID NO:2 is at position 88 of SEQ ID NO:1 and the last nucleotide of the codon that encodes amino acid number 129 in SEQ ID NO:2 is at position 534 in SEQ ID NO:1. Original claim 1(b) recites "a nucleotide sequence encoding a polypeptide comprising amino acids -19 to 129 in SEQ ID NO:2." The first nucleotide of the codon that encodes amino acid number -19 in SEQ ID NO:2 is at position 91 of SEQ ID NO:1 and the last nucleotide of the codon that encodes amino acid number 129 in SEQ ID NO:2 is at position 534 in SEQ ID NO:1. In addition, original claim 1(c) recites "a nucleotide sequence encoding a polypeptide comprising amino acids 1 to 129 in SEQ ID NO:2." The first nucleotide of the codon that encodes amino acid number 1 in SEQ ID NO:2 is at position 148 of SEQ ID NO:1 and the last nucleotide of the codon that encodes amino acid number 129 in SEQ ID NO:2 is at position 534 in SEQ ID NO:1. Accordingly, it is clear that the skilled artisan would have understood the present inventors to have been in possession of the subject matter claimed in claims 53-55.

In addition, support for subparagraph (m) of new claim 21 can be found at page 13, lines 3-17.

Support for claims 34-39 can be found in original claim 17. Support for claims 40-42 can be found at page 12, lines 25-26. Support for claim 43 can be found at page 13, line 19. Support for claims 61-64 can be found at page 14, line 19 to page 15, line 12 and page 23, line 17 to page 24, line 11.

These changes are believed to introduce no new matter, and their entry is respectfully requested.

### ***Objection to the Specification***

The examiner objected to the specification for failing to recite the most recent address for the ATCC. Applicants have amended the specification at page 7 to incorporate the current address for the ATCC depository. Thus, the objection has been overcome and should be withdrawn.

***Objection to the Title***

The examiner objected to the title as not being descriptive of the claimed invention. Applicants have amended the title to recited "Polynucleotides Encoding Chemokine Beta-15." Thus, the objection has been overcome and should be withdrawn.

***Rejections under 35 U.S.C. § 112, First Paragraph***

The examiner rejected claims 8 and 9 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled. Applicants respectfully disagree.

With regard to claim 8, the specification at page 13, lines 4-17 sets forth specific conditions that constitute "stringent hybridization conditions." The specification also describes which polynucleotides would hybridize under "stringent hybridization conditions" to the reference sequence. (See, specification at page 13, lines 4-25). Thus, the examiner's rejection is in error. However, solely in an effort to expedite prosecution, applicants have canceled claims 8 and 9 without prejudice in favor of claim 21 subparagraph (m). Claim 21 subparagraph (m) specifically recites the stringent hybridization conditions that are fully supported at page 13, lines 7-11. Thus, the rejection is moot and should be withdrawn.

***Rejections under 35 U.S.C. § 112, Second Paragraph***

The examiner rejected claims 1 and 8-14 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. It is the examiner's position that

[a]t pages 8, 16-19, and 28-29 of the specification, applicants set forth different percentage that the inventive concept is to encompass and at page 28 merely define what they intend by 'similarity'. . . . Because the sequence identity can be determined by various means and produce different results and different degrees/percents of identity, the skilled artisan would not be able to determine the metes and bounds of the claims . . . .

(Office Action at page 3). Thus, the examiner concludes that the "claims fail to find support by way of a written description in the specification for a reproducible method of how the percent identity is determined."

Applicants respectfully disagree and traverse as applied to claims 21 and 44. The test for indefiniteness is whether the scope of the claim is clear to a hypothetical person possessing an ordinary level of skill in the pertinent art. (M.P.E.P. § 2171.) The language of the claim must reasonably apprise those skilled in the art both of the utilization and the scope of the invention. (*PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558 (Fed. Cir. 1996.) In interpreting language used in a claim, words are to be given their ordinary meaning in the absence of indication in the patent to the contrary. (*Markman v. Westview Instr., Inc.*, 52 F.3d 967 (Fed. Cir. 1995)(*en banc*) *aff'd*, 116 S.Ct. 1384 (1996).)

While it is true that a definition for 'similarity' appears at page 28 of the specification and pages 8, 16-19, and 28-29 describe different percentages of permissible 'identity', the examiner has apparently ignored the fact that the specification does include a description of what applicants intend by 'identity.' In particular, at page 17, lines 1-15, the specification describes both a computer algorithm ( i.e., Bestfit) and parameter settings (i.e., the paramaters are set . . . such that the percentage of identity is calculated over the full length of the reference nucleotide sequence and that gaps in homology of up to 5% of the total number of nucleotides in the reference sequence are allowed) for determining the percent 'identity' between two sequences. Thus, the metes and bounds of the claims are clear.

However, to expedite prosecution, claim 1 has been redrafted as new claims 21 and 44. Subparagraphs (g)-(l) of new claim 21 are exemplary and include the following language:

a polynucleotide variant created by altering the [reference]  
polynucleotide . . . wherein:

- (1) said altering includes a nucleotide insertion, deletion, or substitution, or any combination thereof; and
- (2) the number of alterations is equal to or less than 5% of the total number of nucleotides present [in the reference polynucleotide].

Applicants submit that the above language provides a simple, clear and reproducible method for determining whether any particular polynucleotide falls within the claim. In short, polynucleotides having a number of insertions, deletions, and/or substitutions that is equal to or less than 5% of the total number nucleotides present in the reference polynucleotide meet the claim language. (See, present specification at page 16, lines 20-31). For example, if the reference polynucleotide is 100 nucleotides in length, then the number of alterations, deletions, and/or substitutions of the reference polynucleotide that would be permitted by the literal language of the claim is not more than 5% of 100, i.e., 5. Similarly, if the reference polynucleotide is 124 nucleotides in length, then the number of alterations, deletions, and/or substitutions of the reference polynucleotide that would be permitted by the literal language of the claim is not more than 5% of 124, i.e., 6.

Thus, the metes and bounds of subparagraphs (g)-(l) of new claim 21 and subparagraphs (e)-(h) of new claim 44 are clear and it is respectfully submitted that the rejection be withdrawn.

The examiner contends that "claim 8 is also indefinite and confusing because it is not clear what is meant by the statement that the sequence would consist of only A and T residues." (See, Office Action at page 3, lines 19-20). Applicants traverse.

The recitation in claim 8 that the examiner refers to states "wherein said polynucleotide which hybridizes does *not* hybridize under stringent conditions to a polynucleotide having a nucleotide sequence consisting of only A residues or of only T residues." (Emphasis added). This recitation simply states that hybridization of a polynucleotide to a poly A tail, for example, under stringent hybridization conditions would not be encompassed by the claim. However, solely in an effort to expedite prosecution, claim 8 has been canceled in favor of claim 21 subparagraph (m). Claim 21 subparagraph (m) specifically recites the stringent hybridization conditions that are fully supported at page 13, lines 7-11. Thus, the rejection is moot and should be withdrawn.

***Rejections under 35 U.S.C. § 102 or § 103***

Claims 8 and 9 were rejected under 35 U.S.C. § 102(a) or (b) as anticipated by or, in the alternative under 35 U.S.C. § 103 (a), as being obvious over Adams *et al.* or Hillier *et al.* It is the

examiner's position that the applied art references disclose a sequence that has a substantial amount of sequence identical to the nucleic acid sequence of the claims. It is also the examiner's position that since there is substantial homology, it would be expected that this sequence would encode for an epitope-bearing portion of the encoded protein. Applicants respectfully traverse.

The Hillier *et al.* EST (i.e., N73958), according to the alignment sent by the examiner, is homologous to nucleotides 564 to 960 of SEQ ID NO:1. These nucleotides correspond to the 3' non coding region of the claimed gene (the coding region being nucleotides 88 to 534 of SEQ ID NO:1). Thus, the sequence disclosed by Hillier *et al.* does not encode an epitope bearing region of the protein encoded by the claimed gene because the corresponding region in SEQ ID NO:1 does not code for protein.

In addition, the Adams *et al.* ESTs (i.e., AA295925 and AA295945), according to the alignment sent by the examiner, have homology only to about 120 bp and 223 bp of coding region of SEQ ID NO:1 (AA295925 and AA295945, respectively). The other ESTs in this alignment are homologous to the non coding region of SEQ ID NO:1 (i.e., AA295814 and AA295958).

Claims 8 and 9 have been canceled in favor of new claim 40, which requires "at least 500 contiguous nucleotides from the coding region of SEQ ID NO:1." Applicants submit that the cited Hillier *et al.* and Adams *et al.* ESTs do not disclose a polynucleotide that is identical or highly homologous to 500 contiguous nucleotides from the coding region of SEQ ID NO:1. Therefore, it is respectfully submitted that the rejection should be withdrawn.

#### ***Other Matters***

The examiner indicated that claims 2-7 and 17 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form. The examiner also indicated that claims 1 and 10-14 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. § 112 set forth in the Office Action. Applicants believe that the forgoing amendment and remarks place all the pending claims in condition for allowance.

***Conclusion***

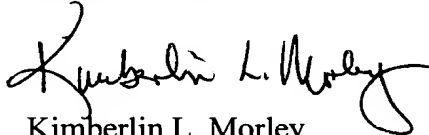
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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